1.0 Purpose:

To ensure continuous provision of quality in the operations of Laboratory Services.

2.0 Scope:

Hospital Wide

3.0 Policy:

The Department of Laboratory Medicine assures accurate and reliable test results by following the established standard operating procedures, to facilitate better diagnosis and treatment of patients .The Department also assures to protect the integrity and safety of its patient and staff.

The department of laboratory services has a planned and systematic set of activities to ensure that variances in process are clearly identified and assessed, thus improving the process for fulfilling the requirements of customers.

Our quality assurance system includes IQC, EQA, test standardisation, Interlab comparison studies and following pre determined set of steps in pre analytic and post analytical phases of sample processing.

4.0 Verification of test methods

Verification is an internal quality process of determining compliance with a standard and it is done in our laboratory by testing for accuracy and precision of test results. Accuracy denotes the degree of closeness of measurements of a quantity to its actual value whereas precision is the degree to which repeated measurements under unchanged conditions show the same result.

Inter lab comparisons are carried out with laboratories which are accredited by standard organisations, before a new test system is used for reporting patient results, along with precision checks and assessment of linearity.

- Inter lab comparisons
- Precision checks
- Linearity

Interlab comparisons are carried out annually and the reviews are documented in the appropriate files. Precision checks are also done for most parameters along with linearity studies and all the reports are properly filed. Accuracy of testing is evaluated by using

samples (commercially prepared) with known values, as in quality controls. The results are evaluated and a new methodology or equipment is initiated only after satisfactory performance is seen in the control runs. Wherever possible, bi or tri-level controls are used.

5.0 Validation of test methods

Validation relates to conformation that the needs of an external customer are met in a high quality manner. Our lab service does an ongoing review of its established methods by performing daily internal quality controls, participating in biweekly/monthly proficiency testing processes run by standard organisations, periodically calibrating our instruments and by reviewing historical data.

6.0 Quality Control

Laboratory adheres to the following steps to ensure reliability and accuracy of the test results.

7.0 Procedure:

Head of Laboratory Services will be involved in the procurement of all chemicals and reagents required by the laboratory.

Calibration of equipments is done strictly as per the recommendations of the equipment manufacturer.

Products recognized and certified by appropriate national and international bodies are only used in the laboratory.

Wherever possible, third party control materials are used as internal and external controls. Two or three level control materials are used to assess the performance of an analyte. Two level control materials are used in routine biochemistry, and three level control materials in coagulation - one control from healthy individual & two controls which are commercially available. For Blood gases, Haematology and Serology also multiple level controls are used.

8.0 Internal Quality Control

It is done once every day in Biochemistry (including blood gases), serology, coagulation and twice a day in Haematology. Acceptance or rejection of run of internal quality control is based on Total Error Concept (based on CLIA 88 total quality acceptance limits and also control material manufacturer acceptance limits)

Acceptable performance target value for analyte is listed in Annexure 1.

9.0 External Quality Assurance

Our laboratory participates in External proficiency testing programmes, conducted by recognised and standard agencies like Biorad and etc. Monthly and biweekly samples are received, analysed and the values send for report generation. The reports are obtained as soft and hard copies, which will rate the lab's analytical accuracy with the predetermined values. The data of the past months are also analysed together and scoring systems are used, which helps the lab in not only assessing its single performance, but also the trend followed in recent times. Based on these reports, which are regularly reviewed, necessary steps are taken, whenever there is a declining trend in any of the parameter analysis.

Samples are regularly sent to the following agencies as well as accredited labs for cross checking of the test results.

Biochemistry:

- EQAS from Bio-Rad (Monthly)
- ILCS (Once in 3 months)

Clinical Pathology:

- ILCS (Once in 3 month) for Urine & Stool

Haematology:

- EQAS from AIMS (Once in 3 month)
- ILCS (Once in 3 months)

10. Surveillance of test results

Surveillance of test results are carried out on a regular basis. The signatory authority systematically reviews results of examinations and evaluate them in conformity with clinical information available regarding the patent. The clinical information is collected verbally in relevant situations and correlation performed. This is documented and filed.

Feedbacks are also periodically collected from outpatients and clinical consultants to improve the quality of services provided and to find out any flaws in the routine system of management.

11. Laboratory Quality Indicators

The following is a comprehensive list of potential laboratory indicators which are monitored to ensure quality:

- Number of errors (Reporting and Technical)
- Number of samples recollected (insufficient quantity, labelling errors, wrong container)
- Total number of investigations done
- PPE Adherence check in Laboratory and Phlebotomy
- Avg. Turnaround Time - Blood Components Issue

- Blood transfusion reactions
- Percentage of waste of Blood and Blood products
- Percentage of Blood component usage
- Patient Waiting Time for Services/Phlebotomy
- Clinical correlation register